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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/323,765	06/01/99	SCOTT M	259.006US1

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EXAMINER	
HAYES, R	
ART UNIT	**PAPER NUMBER**
1647	16

DATE MAILED: 10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/323,765	Applicant(s) Scott et al
	Examiner Robert C. Hayes, Ph.D.	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 13, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above, claim(s) *27, 29, 30, and 32-52* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☒ Claim(s) *1-26, 28, and 31* is/are objected to.

8) ☒ Claims *1-52* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendment filed 7/13/01 has been entered.

2. This application contains claims 27, 29-30 & 32-52 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. The objection of claims 14 & 31 under 37 CFR 1.75(c), as being of improper dependent, is withdrawn due to the amendment of the claims.

4. The rejection of claims 15 & 17-18 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

5. Applicant's arguments filed 7/13/01 have been fully considered but they are not deemed to be persuasive.

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 2-7, 9, 18-19, 23-25, 28 & 31 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,908,624, for the reasons made of record in Paper No.13. The serial number of U.S. Patent 5,908,624 which forms the basis for the double patenting is missing. (See 14.32). Therefore, the terminal disclaimer needs to be resubmitted, in order to obviate this rejection.

8. Claims 14, 19-23, 28 & 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons made of record in Paper No. 13, and as follows.

Similar to that previously made of record, claim 14 contains no proper antecedent basis for a "nuclear" cell, in that base claim 1 is directed toward "anuclear" cells. Additionally, the new recitation of "said linking moieties..." has no proper antecedent basis (i.e., as it relates to claims 19-23 & 28). Claim 31 also remains indefinite because a "platelet" is an "anuclear" cell, and a not "nuclear" cell, as recited in new base claim 2.

9. Claims 2-7, 18-21, 23-25, 28 & 31 stand rejected under 35 U.S.C. 102(e) as being anticipated by Desai et al. (U.S. Patent 5,578,442), for the reasons made of record in Paper No. 13, and as follows.

Applicants argue on pages 9-10 of the response that the "specific limitation [of covalently attached] must be taught by Desai et al. for this rejection to be tenable", and that "both the limitation of 'covalent bonding' and bonding to a 'virus particle' limitation to be absent from the invention contemplated by Desai et al.". In contrast to Applicants' assertions, and as previously made of record, Desai clearly teach "covalent bonding" through, for example, free radical polymerization (i.e., col. 4, lines 40-54; col. 5, lines 13-26), and through UV-crosslinking (e.g., col. 3, lines 57-61). Also, in contrast to Applicants' assertions, no claims recite "bonding to a virus particle". Therefore, Applicants' assertions are moot concerning this point.

Applicants argue further on pages 10-12 that there is an "absence of covalent bonding" in Desai's teachings, and refer to a different embodiment of Desai's invention that relates to "'associates" [with] a polycationic species with the negatively charged cell surface", as illustrated in column 5. However, merely citing a different embodiment of Desai that alternatively contemplates use of ionic interactions has nothing to do with the rejection made of record, and therefore, is moot. It is noted that Applicants' comments that "life as we know it would cease on the Earth" are also inappropriate, and not on point. Applicants' other assertions that "blood cells would bond to vascular walls (e.g., cause clots and strokes), would crosslink tissue (e.g., the lungs), and cause other undesirable activities within the human body", are further off point, and fail to address to rejection made of record in Paper No. 13. Thus, Applicants' arguments are not persuasive.

In contrast, the courts have held that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

Further, the courts have held that "when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product..., a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable". *In re Brown*, 173 USPQ 685 (1972).

Lastly, it should be noted that if a product in the newly recited product-by-process claims 18, 28 & 31, etc. that is "derived from reaction of a cyanuric chloride linking group on the covalently bonded hydrophilic, biocompatible, non-immunogenicity providing compound or polymer to the cell surface", is the same as or obvious from a product of the prior art (i.e., formation of identical non-immunogenic cellular compositions), the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe.,* 227 USPQ 964, 966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

10. Claims 1, 4, 8, 10-16, 24 & 26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Francis et al. (WO 95/06058), for the reasons made of record in Paper No. 13.

It is noted that the instant rejection is not a rejection of claims 1-11 under 35 USC 103(a). Applicants then argue on pages 12-13 of the response that "[a]lthough Francis does apparently

incidentally show the covalent bonding of a moiety (including PEG, the erythrocytes of Example 7) to the surface of a red blood cell, the bonding is done for the purpose of differentiating cells... and only mammalian cells, as opposed to virus particles...". In contrast to Applicants' assertions, the claims are directed toward mammalian cells, in which no limitations involving "virus particles" are claimed. Moreover, the fact that Applicants admit for the record that Francis teach the recited claim limitations, but "done for... [a different] purpose", has no bearing on whether Francis teach the broadly claimed "products" of the instant invention. In other words, Applicants arguments alternatively support the rejection made of record for these claims. *In arguemdo,* it should be noted that extrapolating from one of Francis's non-working embodiments to the conclusion that teachings of Francis as having "been shown to provide a cell composition that is **NOT** non-immunogenic" is a mischaracterization of the record.

Accordingly, the courts have held that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

Further, the courts have held that "when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product..., a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable". *In re Brown*, 173 USPQ 685 (1972).

Lastly, it should be noted that if a product in the newly recited product-by-process claims 14, 28 & 31, etc. that is "derived from reaction of a cyanuric chloride linking group on the covalently bonded hydrophilic, biocompatible, non-immunogenicity providing compound or polymer to the cell surface", is the same as or obvious from a product of the prior art (i.e., formation of identical non-immunogenic cellular compositions), the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe.,* 227 USPQ 964, 966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983).

11. Claims 1, 4, 8, 14-16, 24 & 26 stand rejected under 35 U.S.C. 102(a) as being anticipated by Jeong et al. (1996), for the reasons made of record in Paper No. 13.

Applicants argue on page 13 of the response that "Applicants provide herein an official correspondence from Marcel Dekker clearly identifying the publication date of the Jeong at al. article". In contrast to Applicants' assertions, no such "official correspondence" has been attached to this response. Thus, Applicants' arguments are moot.

12. Claims 1-26, 28 & 31 strand rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al., in view of Francis et al. (WO 95/06058), for the reasons made of record in Paper No. 13, and as follows.

Applicants argue that "Desai et al. has been clearly established as failing to show covalent bonding of PEG to cell surfaces". In contrast to Applicants' assertions, ignoring the actual

rejection made of record in Paper No. 16 does not obviate the teachings of Desai, as discussed above in *pp* #9. Applicants then state that "[t]he Francis et al. reference, showing a specific format for providing covalent bonding of PEG to a cell surface for a purpose other than providing non-immunogenicity, **fails to provide non-immunogenicity by his sole described method**". In contrast to Applicants' assertions, this statement mischaracterizes the teachings of Francis et al.. In other words, the fact that Francis teach alternative methods that allegedly do not "yield any protection from immune recognition" due to the RBCs not being "significantly modif[ied]", as argued on page 12 of the response, has nothing to do with that taught by Desai et al., in view of Francis et al., for the reasons made of record. Thus, Applicants' comments related to Francis "*sole* described method" [emphasis added] are a mischaracterization of the teachings of Francis.

Applicants continue to argue on page 14 that "the purpose for the covalent bonding of compounds to mammalian (*sic*) cell shown by Francis is for a fundamentally different purpose than that shown by Desai". In contrast to Applicants' assertions, the courts have held that "when the prior art discloses *a product* which reasonably appears to be either identical with or only slightly different than a product..., a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable"[emphasis added]. *In re Brown*, 173 USPQ 685 (1972).

In summary, the teachings of Desai et al., in view of Francis et al., clearly give rise to non-immunogenic cells by virtue of the intrinsic properties of the cells made by Desai et al., in

view of Francis et al., which would be non-immunogenic, by definition. In other words, Applicants' arguments do not accurately address the rejection made of record, and therefore, are not persuasive.

Thus, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to include Francis' red blood cells (RBCs), and alternate methods of covalently attaching other non-immunological polymers to cells, in Desai's non-immunological cell compositions, because of the common problems of non-compatible antigenic sites between different species/individuals for both nuclear and anuclear cells (i.e., RBCs and platelets), especially if such tissue/blood is scarce, and because Desai et al. disclose in their Detailed Description of the Invention that "[t]he process of the present invention can be used for rendering non-immunogenic *any* cell, tissue, organ, or system of organs, and the like, that may be used for transplant or the like" [emphasis added] (col. 6, lines 15-18); thereby, providing the motivation for using any cell type, including RBCs and platelets (i.e., as it relates especially to claims 15-23, 26 & 28) as a substrate for making non-immunogenic cell compositions.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
October 1, 2001

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